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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,370	07/08/2003	Neil David Hammond Raven	1581.0990001/RWE/VSR	7846
43320	7590	11/17/2006		
EVAN LAW GROUP LLC 600 WEST JACKSON BLVD., SUITE 625 CHICAGO, IL 60661			EXAMINER WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/614,370

Applicant(s)

RAVEN ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-11 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-11 and 31-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/8/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1, 3-11 and 31-35 are pending.

#### ***Information Disclosure Statement***

The information disclosure statements (IDSs) submitted on August 8, 2006 has been received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner and appropriate fee of \$180.00 charged accordingly per request of Applicants.

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Response to Amendment***

The amendment filed September 7, 2006, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Election/Restrictions***

Non-elected claims 12-30 have been canceled and Applicants maintain their right to file one or more divisional application(s) to the non-elected subject matter.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-11 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Bolton et al (X4) in view of newly cited Taylor (X34), and newly cited Haki et al (X10), all newly cited references cited on newly enclosed PTO-1449 Form, filed August 8, 2006, and Daniel et al (D1), cited on previously enclosed copy of PTO-1449 Form filed June 19, 2006,.

Claims are drawn to a method for inactivating a transmissible spongiform encephalopathy (TSE) agent (i.e. prion) comprising exposing the agent to a thermostable proteolytic enzyme.

Bolton et al teach that scrapie agent or prion (i.e. TSE agent) can be inactivated by protease enzyme, note column 1, lines 22-25. Also scrapie agent studies showed that a protein ("prion") is required for infectivity, column 1, lines 15-25.

The claims differ from Bolton et al in that exposure of the prion to thermostable proteolytic enzyme at a temperature greater than 40 degrees celsius is not disclosed.

Taylor teaches that inactivation of TSE agents or prions involves avoidance of protein-fixation because heat alone is not enough to inactivate prions, note the entire abstract.

Haki et al teach thermostable enzymes, such as protease and their respective properties of pH and temperature, note Table 1, 2, 5, and 6 of pages 18-19 and 22-23. The temperature is greater than 40 degrees celsius and can be as high as 50 and above. The pH can be as high as 10.5, see Table 7, page 25, line 6. Thermostable proteolytic enzymes are disclosed to be from *Bacillus subtilis*, *Bacillus* species, *Thermotoga neopolitana*, etc. Thermostable serine protease is also disclosed at page 24, column 2, line 38.

Daniel et al teach thermophilic proteolytic enzymes from Archae bacteria including *Bacillus* bacteria. Note the entire 27 pages wherein each of temperature and pH are disclosed in Tables 1 and 2.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to expose the TSE agent or prion of Bolton et al to the thermophilic proteolytic enzymes of Daniel et al and Haki et al at a temperature greater than 40 degrees celsius because not only does Haki et al disclose the identical temperature and pH properties for the protease disclosed by Bolton et al but Taylor clearly suggests that protein degradation is required to avoid protein fixation. Bolton et al clearly disclose that protease can deactivate prion TSE agent, such as scrapie which is also identified as a prion. Clearly one of skill would have expected successful results and would have been motivated to select for the enzymes disclosed by Haki et al and

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Daniel because Bolton et al clearly teach that a proteolytic enzyme will degrade a prion agent. Bolton et al would, therefore, be expected to successfully inactivate a prion dimer as well. Proteolytic enzymes are well known to deactivate TSE and one of skill would have been motivated to select these enzymes for this purpose.

To select for thermostable enzymes having stability at higher temperatures is clearly within the purview of an artisan, and Daniel et al disclose their enzymes work above 40 degrees C and also at 75 degrees C, as does Haki et al, which are within the claimed ranges. To select for alkaline pH is also within the purview of a skilled artisan since Haki et al clearly disclose the desired pH ranges of at least 10.5 which is well within the claimed ranges of pH. Further, to select for subtilisin derived from Bacillus bacteria or MC-A, MC-3 and MC-4 is an obvious modification of the cited prior art. In the absence of convincing evidence to the contrary the claims are prima facie obvious over the cited prior art.

### ***Response to Arguments***

The arguments regarding Shenoy et al and Daniels et al are deemed persuasive, however, new art submitted by Applicants on an enclosed PTO-1449 Form has been discovered and is set forth above. Therefore, the claims are rejected over the newly submitted prior art.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on August 8, 2006, prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS**

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**MADE FINAL.** See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

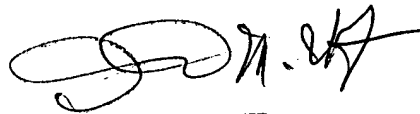
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Deborah K. Ware  
November 11, 2006



DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 128/1657